

REMARKS

The English language application filed herewith is a translation into English of the parent application (International Application No. PCT/EP2004/008168 filed on July 22, 2004). References herein to paragraph numbers of the parent application relate to the English language version.

A. Amendments in the specification

Amendment of the specification by insertion of new paragraph [0000] is requested to provide cross-reference to, claim benefit of, and incorporate by reference prior applications in accordance with 37 C.F.R. §§ 1.55, 1.57(a) and 1.78(a), and to cross-reference and incorporate by reference a concurrently filed U.S. application in accordance with 37 C.F.R. § 1.57(d).

Replacement paragraph [0010] is amended to insert the word “now” in the phrase “It has been shown ...”, in order to further clarify that the specifically antidepressive effect of rotigotine is a showing made by the inventors in accordance with the present invention, and is not a showing of prior art.

Replacement paragraphs [0016], [0020], [0021], [0024], [0026], [0028] and [0029] are amended to recite that the embodiments described therein relate to a method for treating depression in a mammal. Support for this amendment is found in the parent application at least at paragraph [0030] and at Claim 1.

Opportunity is taken to correct minor grammatical and/or syntactical deficiencies in amended paragraphs, some of which may have arisen from translation, and thereby enhance clarity of disclosure of the invention.

B. Amendments in the claims

By amendment of the claims herein, Claims 1–8 are cancelled without prejudice. It will be noted that original Claims 1–8 were presented in so-called “Swiss form”. Applicant elects in the present application to prosecute claims to a method for treating depression, as presented herein in Claims 10–27, but in doing so makes no admission as to patentability or lack thereof with respect to the now cancelled “Swiss form” claims.

The following claims are now pending in the present application: Claims 9–28. Each of these claims finds support in the parent application as filed, as indicated below.

Claim 9, drawn to a combination preparation, is amended to enhance clarity of the claim, for example by providing more standard Markush wording and by deleting the phrase

“for treating depression”, it being recognized that the use to which a preparation is put is not a patentably distinguishing feature of the preparation *per se*. Claim 9 is further amended to recite after rotigotine “or a metabolite, prodrug or physiologically acceptable salt thereof” for consistency with Claim 10 as amended herein (see immediately below). Claim 9 is still further amended to replace “migraine agents” with “anti-migraine agents”. That “anti-migraine agents” is the intent of the original language can be seen from paragraph [0056] of the parent application, which refers to an “anti-migraine effect”.

Claim 10, drawn to a method for treating depression in a mammal, is amended to add, among agents useful according to the method, metabolites of rotigotine. Support for metabolites of rotigotine used in treatment of depression is found in the parent application at least at paragraphs [0028], [0029] and [0030]. By amendment of Claim 10, salts of rotigotine are further specified to be physiologically acceptable. Support for this amendment is found in the parent application at least at paragraphs [0040] and [0041].

New Claim 11 recites that the mammal is human. Support for this recitation is found in the parent application at least at paragraph [0030].

New Claim 12 recites that the depression is an endogenous depression or an organic depression not associated with Parkinson’s disease. Support for this recitation is found in the parent application at least by combining paragraphs [0021] and [0029].

New Claims 13–15 will be seen to correspond substantially to original Claims 2, 4 and 5 respectively. Support for Claims 13–15 is found in the parent application at least in these original claims, and in the specification at paragraphs [0030], [0029] and [0028] respectively.

New Claim 16, drawn to a method of the invention for treating Parkinson’s disease-associated depression wherein co-medication with another antidepressant is absent, finds support in the parent application at least at paragraphs [0027]–[0028].

New Claims 17 and 18 will be seen to correspond substantially to original Claims 6 and 7 respectively. Support for Claims 17 and 18 is found in the parent application at least in these original claims.

New Claims 19 and 20, reciting dosage ranges, find support in the parent application at least at paragraph [0047].

New Claim 21, drawn to a method of the invention wherein a rotigotine prodrug is administered, finds support in the parent application at least at paragraph [0016] and in

greater detail at paragraphs [0031]–[0037].

New Claim 22 will be seen to correspond substantially to original Claim 8. Support for Claim 22 is found in the parent application at least in these original claims, and in the specification at paragraph [0032].

New Claim 23, which recites that rotigotine is administered transdermally as rotigotine free base or hydrochloride salt, finds support in the parent application at least at paragraphs [0040] and [0043].

New Claim 24, which recites transdermal administration by a variety of means, finds support in the parent application at least at paragraph [0043].

New Claim 25, which recites transdermal administration by means of a plaster wherein the active ingredient is present in a matrix comprising an adhesive polymer, finds support in the parent application at least at paragraph [0044].

New Claim 26, which recites transdermal administration of rotigotine wherein a substantially constant plasma level of rotigotine is established, finds support in the parent application at least at paragraph [0044].

New Claim 27, drawn to a method of the invention that further comprises administration of an additional active agent as specified therein, finds support in the parent application at least at paragraphs [0052]–[0056].

New Claim 28, drawn to a combination preparation wherein the further active ingredient is an antidepressant as specified therein, finds support in the parent application at least at paragraphs [0054]–[0055].

Claims 9–28 therefore find support in the parent application as filed. No new matter is introduced by the present amendment. No changes in inventorship are believed to result from the present amendment. Examination of the present application is requested following entry of this amendment.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.



James C. Forbes
Agent for Applicant
Reg. No. 39,457
Tel. 847-412-6350